AUG - 7 2001

GE Medical Systems
General Electric Company
P O Box 414 Milwaukee, WI 53201

K012313

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Submitter Larry A. Kroger, Ph.D.
Senior Regulatory Program Manager
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Date Prepared: June 12, 2001

PRODUCT IDENTIFICATION

Name: CT Colonography/Navigator2

Classification Name: Accessory to Computed Tomography System

Manufacturer : General Electric Medical Systems
283, rue de la Miniere
78533 Buc Cedex, FRANCE

Distributor: General Electric Medical Systems, Milwaukee, WI

Marketed Devices The CT Colonography/Navigator2 is substantially equivalent to the device listed below:

Model:	Navigator
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K954355

Device Description:
CT Colonography/Navigator2 (CTC/Nav2) is an image analysis software package that allows the user to study the inside, wall, and outside of the colon using CT-acquired helical images. The tool is laid out to facilitate the detection of colonic lesions. CT Colonography requires Navigator2 for its operation however, Navigator2 can also be utilized as a stand-alone option. Navigator2 is an advanced visualization software option that provides endoluminal views of anatomical structures. The flexibility of this software allows the user to move interactively from air paths to inner vessels visualization and thus, it is not limited to inner navigation of structures as lungs and sinuses. Volume Analysis (includes both, CT/MR Windows Workstation, K913770 and 3D & Dentascan for Windows K923077) provides the base for CTC/Nav2 and Nav2 alone, which allows an increase in the ease of use and productivity. CTC/Nav2 and Nav2 alone, also use some options of Volume Rendering (AW Volume Render Option

K972399), which allows the user to quickly isolate structure of interest and render volumetric data in three dimensions.

Indications for Use :

CT Colonography/Navigator2 is an image analysis software package that contains CT Colonogarphy and Navigator2.

CT Colonography allows the user to study the inside, wall and outside of the colon. It provides the user with an ability to view datasets from both, prone and supine positions, facilitating detection of colonic lesions. In comparison to colonoscopy, this tool has an advantage of non-invasive depth penetration due to its 3D presentation capability.

Navigator2 provides endoluminal views of anatomical structures. Navigator2 is designed to enhance and modify current image quality, tools, speed and user interface of Navigator for improved productivity. Navigator2 provides a visualization tool to investigate structures (such as polyps, tumors, stones, calcification etc.) within anatomy, airways and organs. Thus, its viewing capability of the inner and outer surfaces of organs as well as within their walls provides additional supplemental information, complementing endoscopy/colonoscopy, to support interpretation and treatment planning. Navigation2 is applicable to X-ray as well as CT/MR.

Comparison with Predicate:

CT Colonography/Navigator2 is an image analysis software built on Navigator 2 features that allows the user to study the inside, wall, and outside of the colon using CT acquired helical images. The tool is laid out to facilitate the detection of colonic lesions. Navigator 2 is a new version of the current GE Navigator, it has improved performance and usability. The functional features of this package are substantially equivalent to that of the following device:

Device Name	FDA Clearance Number
Advantage Windows 3D with Navigator Option*	K 954355

**referred as Navigator in this application*

Adverse Effects on Health :

The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

Conclusions:

The CT Colonography/Navigator2 does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the CT Colonography/Navigator2 to be equivalent to those of Navigator (K954355).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2001

General Electric Medical Systems
% Mr. Reiner Krumme
Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K012313
CT Colonography/Navigator 2 (CT Navigation software package)
Dated: July 18, 2001
Received: July 23, 2001
Regulatory Class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known):

Device Name: CT Colonography

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012313